Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effectiveness of Intravenous Infusion of Methylprednisolone 500 mg pulse with NSAIDs in lumbar disc herniation pain relief

Protocol summary

Study aim
To find out the effect of Methylprednisolone on disc herniation for patients refffering to Imam Khomeini Hospital

Design
Two arm parallel group non randomized trial of 90 patients on phase 2-3

Settings and conduct
Methylprednisolone Sodium Succinate 500 mg pulse in 500 cc of Normal Saline intravenous infusion injection as a single dose for test group in injection site of Emam Khomeini Hospital's neurosurgery clinic . control group will recieve no corticosteroid as pain killer . Patients's pain will be measured and recorded verbally and visually in first week and then monthly untill 6 months

Participants/Inclusion and exclusion criteria
Patients above 18 with lumbar disc herniation visible in MRI and associated with low back pain radiating to lower limb that is lasting 6 months at least and there is no focal neurlogical defect

Intervention groups
Methylprednisolone Sodium Succinate 500 mg pulse in 500 cc of Normal Saline intravenous infusion injection as a single dose for test group in injection site of clinic and control group will recieve no corticosteroid as pain killer but otc ones . patients are advise to rest in bed for 24h and the patients's pain will be measured and recorded verbally and visually in first week and then monthly untill 6 months

Main outcome variables
low back pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211116053077N1**
Registration date: **2022-01-30, 1400/11/10**
Registration timing: **prospective**

Last update: **2022-01-30, 1400/11/10**
Update count: **0**

Registration date
2022-01-30, 1400/11/10

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-01, 1400/11/12

Expected recruitment end date
2022-03-03, 1400/12/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Intravenous Infusion of Methylprednisolone 500 mg pulse with NSAIDs in lumbar disc herniation pain relief

Public title
The effect of methylprednisolone pulse in patients with lumbar disc herniation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Lumbar disc herniation visible in MRI Age above 18 History of low back pain radiating to lower limb in last 6 months Filling out informed consent form
Exclusion criteria:
Age under 18 Focal neurologic disorders existence History of vertebral surgery
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences
Street address
Ilam - Bangangab - Research Blvd.
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ilam
Province
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Postal code
6939177143
Approval date
2021-10-23, 1400/08/01
Ethics committee reference number
IR.MEDILAM.REC.1400.152

Health conditions studied

1

Description of health condition studied
Intervertebral disc disorders with radiculopathy, lumbar region
ICD-10 code
M51.16
ICD-10 code description
Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description
Evaluation of pain relief in patients
Timepoint
The patient's condition is assessed one week after treatment, two weeks, three weeks, and one month and six months after treatment.
Method of measurement
MRI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Methylprednisolone Sodium Succinate 500 mg (Lyomedrol EXIR) pulse in 500 cc of Normal Saline intravenous infusion injection as a single dose in 1 hour for test group . Patients will be advised to rest in bed for 24h and avoid heavy physical activities . patients will be taught wilson exercises to relieve their pain
Category
Treatment - Drugs

2

Description
Control group: There will be prescribed oral Diclofenac Sodium 100 mg (Alfen XL Alborz Darou) daily and Patients will be advised to rest in bed for 24h and avoid heavy physical activities . patients will be taught wilson exercises to relieve their pain
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ilam University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available